IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Yong D. Zhao Examiner: Alter, Alyssa M.

Serial No. 10/668,789 Group Art: 3762

Filing Date: September 23, 2003 Docket No.: P0010040.00

Title: MEDICAL ELECTRICAL LEAD SYSTEM INCLUDING PRE-FORMED

J-SHAPED STYLET

Corrections to Appeal Brief

MAIL STOP Appeal Brief - Patents Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The following Appeal Brief is submitted pursuant to the Notice of Non-compliant Appeal Brief mailed March 2, 2010.

Substitute Sections III, VI and VII are attached.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

III. Status of the claims

Claims 1 - 30 are pending.

Claims 9 - 16 and 24 - 30 are presently withdrawn.

Claims 1 – 8 and 17 – 23 stand rejected under 35 U.S.C. 103 as obvious over Williams (U.S Patent No. 4.498.482).

Claims 1 – 4, 8 and 17 - 20 Stand rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013).

Claims 5-7 and 21-23 stand rejected as obvious over Dutcher in view of Hartley (US 20040073141 A1).

All rejections of Claims 1 – 8 and 17 - 23 are hereby appealed.

As claims withdrawn claims 9-16 and 24-30 depend upon claims 1 and 17 which are respectfully asserted to be allowable, allowance of these claims is also respectfully requested.

VI. Grounds of rejection to be reviewed on appeal

1. Rejection over Williams

Claims 1 – 8 and 17 – 23 stand rejected under 35 U.S.C. 103 as obvious over Williams (U.S Patent No. 4,498,482).

Applicants respectfully traverse this rejection.

2. Rejection over Dutcher

Claims 1 – 4, 8 and 17 - 20 Stand rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013).

Applicants respectfully traverse this rejection.

3. Rejection over Dutcher and Hartley

Claims 5-7 and 21-23 stand rejected as obvious over Dutcher in view of Hartley (US 20040073141 A1).

Applicants respectfully traverse this rejection.

VII. Argument

1. Rejection over Williams

Claims 1-8 and 17-23 stand rejected under 35 U.S.C. 103 as obvious over Williams (U.S Patent No. 4,498,482).

Applicants respectfully traverse this rejection.

The rejection over Williams is expressly based upon the argument that it would be obvious to add a curve to the tapered portion of the Williams stylet in order to enhance the ability of the stylet to enhance maneuverability. This argument is contrary to the express teaching of the Williams patent, wherein the tapered portion is intended to allow the stylet to rotate smoothly within a J-shaped lead. Adding a preformed curve to such a stylet would frustrate the basic purpose of the stylet, which is to advance the fixation helix without causing the distal end of the lead to move about. Adding the Examiner's proposed J-shaped curve would cause the distal end of the lead to whip about as the stylet was rotated. Any pacing lead designer, or indeed any lay-person giving the matter a moment's thought, would recognize that this is so. Modifying the Williams stylet as proposed by the Examiner would make it unsuitable for its disclosed purpose and thus cannot be obvious.

Further, the teaching of the Dutcher patent discussed below is entirely consistent with this the teaching of Williams on this point. The pre-curved portion of the Dutcher stylet is not rotated during advancement of the fixation helix, precisely to avoid this problem. Thus, Dutcher also teaches against modifying the Williams stylet as suggested by the Examiner.

While the oft cited KSR decision allows the Examiner to use common sense in combining references, it also imposes the requirement that the Examiner actually demonstrate that the rejection conforms to common sense. The Examiner is referred to the recently published case of Perfect Web Technologies, Inc. v. Infousa, Inc., which explicitly sets forth this requirement.

The Examiner's proposed modification of the Williams stylet is contrary to the teaching of Williams, contrary to the teaching of Dutcher and contrary to common sense. Withdrawal of the rejections of claims 1 – 8 and 17 – 23 as obvious over Williams is therefore also respectfully requested.

Rejection over Dutcher

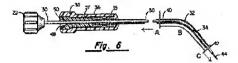
Claims 1 – 4, 8 and 17 - 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Dutcher (US 4,381,013).

Applicants respectfully traverse this rejection.

The claims require a stylet having a straight proximal segment, a curved intermediate segment extending from the proximal segment and a straight distal segment extending from the curved segment. All three segments are clearly visible in Dutcher. The straight proximal and distal segments are plainly visible in the inserted drawing. The area intermediate the straight segments is curved, as required by the claims.

The claims further require a taper zone displaying a decrease in diameter and extending within the intermediate, curved segment. It is indisputable that the taper in the Dutcher stylet is present only in a straight distal segment of the stylet, directly contrary to the requirements of the claims. The Examiner's arguments do not dispute this fact.

The Examiner characterizes Dutcher as having a taper zone extending within a "curved intermediate segment" based upon inclusion of the entire portion identified as B as the "curved segment" required by the claims.



However, as is plainly shown, the portion of B which includes the taper (reduction in diameter) is in fact straight and disclosed as deliberately so. In essence, the Examiner's argument is that if one calls the straight distal segment of Dutcher part of a

"curved segment", the required taper of the present claims is now magically present in the "curved segment" of the claims. The <u>labeling</u> of the portions of the in Dutcher lead does not make the <u>structure</u> as illustrated anticipatory. The claims are not directed to a a taper extending into a "labeled stylet portion including a curved segment."

The examiner's response is that "the claim does not require that the taper is in a curved **portion** (emphasis added) of the curved segment." It is respectfully asserted that if a taper (reduction in diameter) located only along a straight part of a stylet can be interpreted as extending within a "curved segment" of a stylet, it correspondingly can be interpreted as extending along a "curved portion of a curved segment", if the "curved portion" is also interpreted as including the straight part. Rather than supporting the grounds for rejection, the Examiner's argument proves its inappropriateness.

It may be that the Examiner may be relying on some vagueness in the Dutcher patent with regard to the shape of the stylet. It is noted that to the extent the Dutcher disclosure is unclear it cannot be relied upon in an anticipation rejection. Anticipation requires more than simply not disclosing the contrary of the claimed invention.

The simple fact of the matter is that the taper (reduction of diameter) of the Dutcher stylet as disclosed extends only along a straight part of the stylet. The Examiner's interpretation of the claims is unreasonable based both upon normal English usage and in light of the disclosure of the present application, which clearly discloses embodiments in which tapers (reductions in diameter) extend along curved segments, portions, zones, parts or whatever else they may be called.

Withdrawal of the rejections of claims 1 – 4, 8 and 17 – 20 as anticipated by Dutcher is respectfully requested.

Rejection over Dutcher and Hartley

Claims 5-7 and 21-23 stand rejected as obvious over Dutcher in view of Hartley (US 20040073141 A1).

Appl. No. 10/668,789 Appeal Brief Page 7 of 7

Applicants respectfully traverse this rejection.

As the rejections under Section 103 based in part on Dutcher rely on the underlying rationale for anticipation, these rejections are also believed unsupportable.

Withdrawal of the rejections of claims 5-7 and 21-23 as obvious over Dutcher in view of Hartley is therefore also respectfully requested.

With allowance of claims 1 and 17, the withdrawn claims dependent thereon should also be allowed. Allowance of withdrawn claims 9 – 16 and 24 – 30 is therefore also respectfully requested.

Respectfully submitted

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